

WILMERHALE

June 23, 2015

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Honorable Naomi Reice Buchwald
United States District Judge
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street, Room 21A
New York, NY 10007-1312

Re: *In re Intercept Pharmaceuticals, Inc. Sec. Litig.*, No. 1:14-cv-01123-NRB

Dear Judge Buchwald:

We write in response to Plaintiff's June 15, 2015 letter-motion (Dkt. No. 52) requesting a pre-motion conference or briefing schedule for Plaintiff to move to compel the production of documents in the above-captioned action. Plaintiff seeks an order to compel a broad production of (1) *all* internal documentation regarding the potential or expected revenues and earnings from Intercept Pharmaceuticals, Inc.'s ("Intercept" or the "Company") sales of obethicholic acid ("OCA") in the event the drug is approved; and (2) *all* documents regarding (a) insider stock sales and policies, (b) stock offerings, (c) the intended use and burn rate of proceeds from those offerings, (d) potential or actual acquisitions involving Intercept, (e) budgets and financial plans, and (f) the estimated or actual funds needed to complete the development and commercialization of OCA. *See* Ex. B at Request Nos. 25-30, 34-35.¹ As to the former category, Plaintiff contends that the documents are relevant to the putative class's perception of materiality, and, as to the latter categories, he contends that the documents allegedly are relevant to Defendants' motive and opportunity to commit securities fraud—even though his Complaint (Dkt. No. 26) ("Compl.") only alleged such a claim with respect to stock offerings and this Court rejected it.² As set forth below, Plaintiff is engaging in an improper fishing expedition into issues that are irrelevant to the surviving claims or defenses in this case. Discovery on these topics should be denied.³

¹ All citations to "Ex. ____" refer to exhibits attached to Plaintiff's June 15, 2015 letter-motion (Dkt. No. 52).

² Plaintiff's request with regard to any stock sales by Individual Defendants Mark Pruzanski and David Shapiro also seeks *all* documents regarding their "severance package, termination agreement or parachute payments," "loans of Intercept stock or options," "bonuses and/or other compensation policies, terms and agreements," "performance reviews," "benchmarking of salaries against peer groups, and "all payments, loans or taxable benefits received from Intercept." Ex. B at Request No. 25. As with their stock sales, the Complaint never alleges that any of these matters provided either Individual Defendant with a motive or opportunity to commit securities fraud.

³ "[T]he party seeking discovery bears the burden of initially showing relevance." *Mandell v. The Maxon Co.*, No. 06 CIV. 460 (RWS), 2007 WL 3022552, at *1 (S.D.N.Y. Oct. 16, 2007) (citation omitted). Only "[o]nce relevance has been shown, it is up to the responding party to justify curtailing discovery." *Cohen v. City of New York*, No. 05 CIV 6780 RJS JCF, 2010 WL 1837782, at *2 (S.D.N.Y. May 6, 2010) (citation omitted). "Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense . . ." Fed. R. Civ. P. 26(b)(1). This language was introduced in 2000 to "signal to the parties that they have no entitlement to

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Factual and Procedural Background: Plaintiff brings this putative class action lawsuit against Defendants Intercept, Mark Pruzanski (“Pruzanski”), and David Shapiro (“Shapiro”), alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”). The facts of this case are set forth in this Court’s March 4, 2015 Memorandum and Order (Dkt. No. 38) (“Mem.”), at 1-7. This case as pleaded is quite narrow, based on a single alleged omission related to the interim results of a drug trial for OCA (“FLINT”). Intercept issued a press release on January 9, 2014 that disclosed that the National Institute of Diabetes and Digestive and Kidney Diseases (“NIDDK”) had elected to halt the FLINT trial because it showed that OCA had reached its efficacy endpoint. Plaintiff alleges that because the press release did not also include as-then unspecified information on lipid abnormalities observed in trial subjects, Defendants violated the Exchange Act.

In its Memorandum and Order, this Court considered Plaintiffs’ several theories of scienter. While the Court did not dismiss the Complaint, it rejected Plaintiff’s sole motive-based theory of scienter—that Defendants fraudulently inflated Intercept’s stock ahead of an April 2014 secondary stock offering. *See* Mem. 13-16. Notwithstanding this ruling, Plaintiff issued discovery requests to Defendants and third parties regarding the secondary stock offering and other matters that have no relevance to the surviving allegations in this case. The parties have met and conferred numerous times and have not been able to reach a resolution.⁴

Documents Regarding Revenue and Earnings for OCA Are Not Relevant: Plaintiff argues that internal Intercept documents regarding the “actual, potential or expected revenue or earnings from the marketing, licensing or sale of OCA for any indication” are relevant to the materiality of Intercept’s omission of lipid abnormalities. (Dkt. No. 52 at 3.) However, Plaintiff has never alleged that Defendants misrepresented, or even discussed, Intercept’s expected revenues or earnings from OCA in the public statements at issue here. In fact, Intercept has never provided guidance on the potential revenues or earnings from the sale of OCA for NASH. It has not even predicted a launch date for the product. *Matrixx Initiatives, Inc. v. Siracusano*, ___ U.S. ___, 131 S. Ct. 1309 (2011) (“*Matrixx*”) and *City of Livonia Emps.’ Ret. Sys. v. Wyeth*, 284 F.R.D. 173 (S.D.N.Y. 2012) (“*Livonia*”) do not help Plaintiff’s cause. The plaintiffs in those cases sought internal safety information regarding the drugs in question, not internal financial information. In assessing the materiality of that internal safety information, the courts cited only *publicly known* financial information. *See Matrixx*, 131 S. Ct. at 1323 (defendant “told the

discovery or develop new claims or defenses that are not already identified in the pleadings.” *Id.* 2000 Committee Notes.

⁴ Defendants disagree with Plaintiff’s description of the procedural background, as it contains inaccuracies and misrepresentations of the record. For example, without any basis, Plaintiff characterizes the lipid abnormalities as a “major safety risk.” (Dkt No. 52 at 2.) There is nothing in the pre-disclosure correspondence between the NIDDK and Intercept nor in the NIDDK’s own January 10, 2014 press release that characterizes the lipid abnormalities as a “safety risk” let alone a “major” one that might threaten FDA approval of OCA.

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market that its revenues were going to rise 50 and then 80 percent” but chose not to disclose safety information about its leading revenue-generating product); *Livonia*, 284 F.R.D. at 183-84 (drug “was highly touted as a major revenue-maker” but safety information was omitted). Thus, in the absence of a claim that financial information was misstated, the only information about expected revenues that could be relevant to materiality is what was publicly disclosed and known to the putative class. Intercept’s internal information about its financial prospects does not alter the “total mix of information” considered by members of the class.

More fundamentally, OCA’s financial prospects have nothing to do with any claim or potential defense in this case. The Complaint is narrowly focused on the omission of lipid abnormalities during a two-day period, *see* Compl. ¶ 73, and Intercept has not claimed and will not claim that OCA was unimportant to the Company or to its investors. Instead, Intercept’s disclosures were neither misleading nor made with fraudulent intent due to the incompleteness of the lipid information available to Intercept at that time, the publicly-known relationship between OCA and the lipid findings, the NIDDK’s approval of Intercept’s press release, and other factors unrelated to predicted revenues for OCA. Consequently, Plaintiff’s discovery request is nothing more than an improper fishing expedition going beyond the issues in this case. *See In re Top Tankers, Inc. Sec. Litig.*, 528 F. Supp. 2d 408, 419 (S.D.N.Y. 2007) (“There will be no fishing expedition during discovery beyond the matters that are specifically placed at issue in the corrected and amended complaint.”); *Wells Fargo Bank, N.A. v. Konover*, No. 3:05CV1924 CFD/WIG, 2009 WL 585430, at *5 (D. Conn. Mar. 4, 2009) (party cannot “roam in shadow zones of relevancy and to explore matter which does not presently appear germane on the theory that it might conceivably become so.”) (citation omitted).

Plaintiff finally argues that Defendants have asserted that the lipid abnormalities were not material. However, Defendants have never made this argument.⁵ Instead, Defendants argued in their motion to dismiss that at the time Intercept issued its disclosures, Intercept was not in the position to determine whether the lipid changes would have any impact on the question of paramount importance to investors, namely, *the likelihood that the FDA would approve OCA*. *See* Dkt. No. 30 at 19. Expected revenues for OCA have nothing to do with the prospects for FDA approval or the effect that lipid abnormalities might have on those prospects.⁶

Documents Regarding Defendants’ Motive And Opportunity Are Not Relevant: As described at the outset of this letter, Plaintiff seeks a litany of documents supporting his purported claims of motive and opportunity. But the Complaint makes absolutely no claim of

⁵ Defendants have agreed to produce all documents regarding the clinical importance *vel non* of the lipid findings.

⁶ In *In re BioScrip, Inc. Securities Litigation*, No. 13-cv-6922, 2015 WL 1501620 (S.D.N.Y. Mar. 31, 2015), defendants argued that an alleged misstatement “was immaterial because the lost revenue attributable to the major client’s departure was a mere 4.7 percent of BioScrip’s second quarter revenue.” *Id.* at *21. Where defendants put company revenue at issue, such information would be discoverable. But Defendants make no such argument here.

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motive and opportunity other than with regard to Intercept's secondary stock offering, which this Court rejected. *See* Mem. at 13-16. Plaintiff's discovery requests on these topics are improper for several distinct reasons and are just the sort of "fishing expedition" for unpleaded claims that courts have time after time rejected.

First, Fed. R. Civ. P. 26 explicitly cabins discovery to the *claims* and *defenses* in this litigation. *See* Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense"). This language was introduced in 2000 "to address concerns about overbroad discovery." *Id.* 2000 Committee Notes; *see also id.* ("The rule change ... signals to the parties that they have no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings.").⁷ Accordingly, Plaintiff's discovery requests should be denied for this reason alone.⁸

Second, this Court made it abundantly clear in its Memorandum and Order that Plaintiff's sole pleaded motive theory was insufficient under the Private Securities Litigation Reform Act ("PSLRA"):

[T]he timing of the secondary offering—"planned" in January 2014 and not completed until four months later—does not expose a clear motive to commit fraud; rather, the allegation that Intercept would deliberately choose not to discuss lipid abnormalities in the hope of inflating a secondary offering several months away is too attenuated to create the requisite strong inference of scienter, particularly given that Intercept promised to release full findings from NIDDK as soon as they were available.

Mem. 15. Plaintiff argues that Court did not technically strike this lone motive claim from the Complaint; however, courts have rejected just this type of hyper-technical reasoning. For example, in *In re Clorox Co. Securities Litigation*, the court "unequivocally held that only two allegations provided any basis for a colorable claim," but did not partially dismiss the complaint. 283 F. Supp. 2d 1139, 1143 (N.D. Cal. 2002).⁹ The plaintiffs contended that as a result, "all

⁷ Under good cause, this Court has the power to "order discovery on any matter relevant to the subject matter involved in the action." Fed. R. Civ. P. 26(b)(1). But Plaintiff has not shown good cause, especially since the subject matter concerns Intercept's disclosures and the lipid abnormalities, not projected revenues from OCA.

⁸ *See, e.g., Silva v. Pioneer Janitorial Servs., Inc.*, 2011 WL 4729783, at *1 (D. Mass. 2011) (denying motion to compel because the information sought was not relevant to claims or defenses at issue); *Thibault v. Bellsouth Telecomms., Inc.*, 2008 WL 4808893, at *3 (E.D. La. 2008) (courts consider document requests not in the abstract "but rather with respect to the specific claim being asserted"). Plaintiff cites *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340 (1978) for the notion that discovery is not limited to the pleadings, but *Oppenheimer* predates the 2000 amendments to the Federal Rules by 22 years.

⁹ *Aff'd sub nom. Employers Teamsters Local Nos. 175 & 505 Pension Trust Fund v. Clorox Co.*, 353 F.3d 1125 (9th Cir. 2004).

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allegations in the complaint are proper subjects of discovery.” *Id.* The court disagreed, stating that “[t]he PSLRA was enacted in part to curb abusive discovery,” and that “[t]his purpose would be entirely thwarted if a plaintiff could obtain discovery on a litany of meritless assertions simply by attaching them to one narrow colorable allegation.” *Id.*¹⁰ *In re Clorox’s* logic applies here with equal force.¹¹

Third, and finally, Plaintiff prematurely speculates about how Defendants might respond in a summary judgment motion or at trial to Plaintiff’s claims of scienter. Certainly, it is beyond dispute that Plaintiff has not pleaded a claim of motive and that this Court rejected the one that he tried to assert. But, speculation about anything else cannot justify a fishing expedition on matters not articulated in the Complaint or in the Answer. A plaintiff cannot obtain far-reaching discovery simply by speculating about a defendant’s possible strategy.¹²

Conclusion: For the foregoing reasons, Defendants respectfully request that the Court deny Plaintiff’s requests for documents.

¹⁰ Plaintiff omits material portions of his quotation of *In re JDS Uniphase Corp., Sec. Litig.*, No. C-02-1486, 2007 WL 419504 (N.D. Cal. Jan. 31, 2007). The full quote says: “This motion concerns the standard of relevance in discovery of a case that has survived a motion to dismiss, not the sufficiency of allegations to withstand a motion to dismiss under the PSLRA, which imposes a heightened pleading standard.” *Id.* at *2 (italics corresponding to omissions). Here, Plaintiff’s motive and opportunity allegations did *not* survive a motion to dismiss.


¹¹ See also *Spencer Trask Software & Info. Servs. LLC v. RPost Int’l Ltd.*, 383 F. Supp. 2d 428, 463 n.20 (S.D.N.Y. 2003) (“In response to the defendants’ request that the Court limit discovery to the claims that have survived the motion to dismiss..., discovery is, obviously, so limited.”). Plaintiff also argues that he is entitled to discovery because “any evaluation of scienter must be done holistically and take into account all facts” (Dkt. No. 52 at 4), but this cannot mean that discovery on scienter has no limits; instead, Plaintiff is entitled to explore scienter on the grounds that were alleged in the Complaint and sustained by this Court. Any other result would eviscerate the underlying goal of the PSLRA of curbing abusive discovery. See *In re Clorox*, 283 F. Supp. 2d at 1143.

¹² Defendants also plan to move for a protective order under Fed. R. Civ. P. 26 deeming the foregoing matters irrelevant to this action and to preclude third party discovery on the these topics. (Before Plaintiff filed his letter-motion, counsel for Defendants advised counsel for Plaintiff that Defendants planned on requesting a protective order in their opposing letter-motion.) To date, Plaintiff has issued 27 subpoenas to third parties seeking irrelevant documents, and he claims that he has received 425,000 pages of documents from such parties. Dkt. No. 52 at 2. The review of this volume of irrelevant information, and the depositions that would follow, imposes undue burdens on Defendants by raising attorney and vendor fees, imposes unwarranted burdens on Company personnel to assess and explain the matters discussed in these documents, and constitutes an unfair distraction to Defendants whose focus is needed on the core issues and claims actually made in this case. See *Auto-Owners Ins. Co. v. Se. Floating Docks, Inc.*, 231 F.R.D. 426, 429 (M.D. Fla. 2005) (“As parties, Defendants clearly have standing to move for a protective order if the subpoenas [to third parties] seek irrelevant information.”).

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Respectfully submitted,

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cc: Tor Gronberg
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